Message

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Sent: 6/7/2019 3:01:26 PM
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Subject: News Articles (For EPA Distribution Only)

BNA DAILY ENVIRONMENT REPORT ARTICLES

Counties' Lead Paint Nuisance Claims Belong in State Court

By Peter Hayes

Posted June 6, 2019, 11:55 AM

Atlantic Richfield Co., E.I. Du Pont de Nemours and Co., NL Industries Inc., PPG Industries Inc., and Sherwin-Williams Co. will have to defend lead paint public nuisance claims brought by two Pennsylvania counties in state court, the Eastern District of Pennsylvania said.

CHEMICAL WATCH ARTICLES

Maine votes to act on PFASs, phthalates in food packaging

Bill would also give state disclosure, phase-out authority over other 'priority chemicals'

6 June 2019 / Food contact, PFCs, Phthalates, US states

Maine's legislature has approved a bill to eliminate the use of phthalates and PFASs in food packaging and to put in place a system to assess other substances of concern in those materials.

The measure (LD 1433) was approved by both chambers of the state's legislature earlier this week and will head to governor Janet Mills for her consideration.

If signed into law, the bill will ban from 2020 the sale of any food packaging that includes an ink, dye, pigment, adhesive, stabiliser, coating, plasticiser or any other additive to which a phthalate has been "intentionally introduced in any amount greater than an incidental presence".

Covered materials include plastic disposable food service gloves, food and beverage packaging and components thereof, such as coatings, closures, inks and labels.

The legislation also authorises the state's Department of Environmental Protection to establish a rule prohibiting the sale of such packaging to which per- and polyfluoroalkyl substances (PFASs) have been intentionally added, provided that a safer alternative is identified.

Both substance bans would carry a requirement that a replacement substance not present an equal or greater hazard than the one being eliminated.

Priority chemicals

Beyond action on these two classes of substances, the bill also seeks to put in place a scheme for routinely determining substances of concern and requiring disclosure and consideration of possible restrictions on those.

Namely, the legislation would charge the department with creating and periodically updating a list of ten "food contact chemicals of high concern", taking into consideration certain hazard and exposure criteria.

From this list, the state could determine "priority food contact chemicals". Businesses that manufacture or distribute products containing such substances above *de minimis* levels would be required to report on that usage, including details on the number of units sold, the volume of priority chemical used and its intended purpose in the packaging.

The legislation would also authorise the state to impose regulations that prohibit food packaging containing a priority chemical, provided there is evidence that the distribution of the product "directly or indirectly exposes consumers" to the concerning substances, and that a safer alternative is available at a comparable cost.

The action comes on the heels of Washington state's 2018 adoption of a law to ban PFASs in food contact materials. As in Maine, Washington's ban would take effect from 1 January 2022, contingent on the state's ecology department identifying a safer alternative.

San Francisco, California has also adopted a city-wide ban on the sale of single-use food servicewear containing PFASs, which is set to come into force next year.

Retailers, meanwhile, are facing increased scrutiny of substances of concern in food packaging. Last year, grocery chains Whole Foods and Trader Joe's both announced steps to phase out certain PFAS-containing products following an NGO report.

Kelly Franklin

North America editor

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- Washington takes aim at PFASs in food packaging, firefighting foams
- San Francisco bans single-use food service ware containing PFASs
- 'Likely presence' of PFASs found in Albertsons products
- Two US grocery chains pledge action on PFAS takeout packaging
- NGO Platform: PFAS chemicals, a sticky issue for grocery chains

Further Information:

- LD 1043
- Bill text, as amended

US NGO petitions for sunscreen ingredient biomonitoring

6 June 2019 / Exposure monitoring & measurement, United States

NGO the Environmental Working Group has petitioned the US Centers for Disease Control and Prevention (CDC) to add common sunscreen ingredients to its biomonitoring programme.

The group cited the recently published findings of a US Food and Drug Administration study on the absorbency of certain sunscreen ingredients as supporting "the need for biomonitoring of the US population, as well as additional studies to determine the significance of these findings in people."

The sunscreen ingredient oxybenzone is already included in CDC biomonitoring tests. But the EWG has asked that the agency expand this to 12 other ingredients:

- ecamsule;
- avobenzone;
- octocrylene;
- homosalate;
- octisalate;
- octinoxate;
- cinoxate;
- dioxybenzone;
- ensulizole;
- meradimate;
- padimate O; and
- sulisobenzone.

This list largely aligns with the 12 substances the FDA identified in a February proposed rule as lacking information sufficient to establish that they are 'generally recognised as safe and effective' (Grase). The agency has requested more information from manufacturers to address identified data gaps.

Related Articles

- Blood levels of oxybenzone from sunscreen exceed US FDA threshold
- US FDA questions ingredient safety in sunscreen regulations update

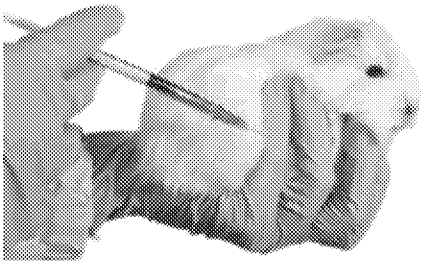
Further Information:

- Petition

China consults on measures to waive animal testing for imported cosmetics

New regulation could be published this year

6 June 2019 / China, Personal care, Product testing, Test/non test methods



China's National Medical Products Association (NMPA) is consulting until 15 June on a first draft of measures that would waive the mandatory requirement for pre-market animal testing on imported non-special use cosmetics.

Non-special use – or general use – cosmetics are those classified as not containing high risk ingredients. Shampoo and perfume are examples of general use cosmetics.

A second draft is likely to be released based on the comments received during consultation, according to Mette Knudsen, CEO of Shanghai-based certification and regulatory compliance consulting company Knudsen & CRC.

But she adds that the authorities might not produce a second draft. Instead, they may just take into account the comments they receive and release a final version. And, if that happens, industry may see the new regulations being completed this year.

Waiving but not banning animal testing

According to the draft Administrative Measures for the Filing of Non-special Use Cosmetics, if a manufacturer has an official Quality Management System (QMS) certificate – and risk assessment results can confirm the safety of the product – the manufacturer would be exempt from providing the relevant toxicology tests for the product. They are still required if:

- the product is declared for use by children or infants;
- the product uses a new ingredient that has been approved or filed, but the ingredient has not been included in the Inventory of Existing Cosmetic Ingredients in China (IECIC);
- the filer, domestic responsible person and the manufacturer are listed as key targets for supervision; and
- the filer, domestic responsible person or manufacturer has been investigated and penalised for the quality and safety of cosmetics within the past three years.

The draft measures have been welcomed in some quarters. Erin Hill, President of the US-based non-profit research and testing laboratory, the Institute of *In Vitro* Sciences (IIVS) says this will have a "huge effect" on industry and "many foreign companies will start importing into China". This effect was seen when mandatory animal tests were waived for domestic manufacturing of cosmetics in 2014.

Ms Hill notes that it greatly reduces what some companies deem a 'trade barrier' and will allow for "significant market expansion" for companies that have previously not entered the Chinese market because of mandatory animal testing.

But this is not the end of animal testing for cosmetics in China, Dr Knudsen warned. "I think we're a long way from a ban. That's what everyone is waiting for, but it's a long walk away," she added.

The IIVS has been collaborating with China's National Institute for Food and Drug Control (NIFDC) since 2014 to help establish better infrastructure to develop proficiency and capacity in non-animal test methods. Ms Hill told Chemical Watch that IIVS provides Chinese regulatory specialists with annual training on internationally-accepted alternative methods.

QMS certificate – a new trade barrier for SMEs?

The draft measures set a new requirement for companies looking to import cosmetic products – they must provide a QMS certificate for any overseas production facilities. The measures do not provide further details on this certificate.

This new requirement is expected to create issues for small-and medium-sized enterprises (SMEs), Dr Knudsen said.

This is because not all countries automatically issue QMS certificates. "Some countries have them and a lot of countries have trade associations that may be able to issue them, but then [there are] some countries that don't even have these certificates," she added.

SMEs are often reliant on third-party manufacturers to obtain QMS certification and therefore have limited leverage. This could create a trade barrier, she said.

While the QMS certificate requirement is an issue, it is not as big a barrier as the animal test issue, Dr Knudsen said. "What we see now is extremely positive with regards to ending animal testing in China," she added.

Background

The draft Administrative Measures for the Filing of Non-special Use Cosmetics form part of the overarching cosmetics regulation – the Cosmetics Supervision and Administration Regulation (CSAR). This is also in draft form and is expected to be released within the next two years.

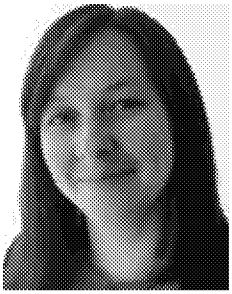
For a cosmetic ingredient to be used in China it must be approved by the NMPA or already be included on China's Inventory of Existing Cosmetics Ingredients (IECIC). The list contains 8,783 ingredients, but only ten have been approved in the last 15 years, with no new updates since 2015.

According to industry experts, the current lack of general rules for approval has led to slow progress and delays to innovation in the cosmetics industry.

The revisions to the CSAR will simplify many procedures and reduce the data requirements for cosmetic ingredients and products. Industry hopes it will help address many of the issues surrounding slow ingredient approvals.

Ms Hill said she was surprised to see the latest measures released ahead of the revised CSAR. She said it is possible to interpret the current consultation as a sign that the authorities "wish to get the new draft finalised quickly after the Cosmetic Supervision and Administration Regulation comes into effect."

In December last year, the government adopted a scheme that simplified the method of obtaining a licence for cosmetics registrations. The government began testing the scheme as a pilot project in the Shanghai Free Trade Zone before expanding it. Dr Knudsen believes the government could take the same approach for these measures, but stresses it is currently "difficult to know for sure what approach they will take."



Ellen Tatham

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- CFDA releases amended cosmetics inventory
- Lack of 'general rules' slowing progress in China's cosmetics industry
- China simplifies general cosmetic imports
- Chinese changes 'real opportunity' to end animal testing of cosmetic imports
- China extends simplified cosmetic import rules to free trade zones

OECD to publish high-level guidance on safer alternatives

6 June 2019 / Alternatives assessment & substitution, Global, Substances of concern

An ad hoc group set up by the OECD is working on "high-level, short and concise" guidance to identify safer and sustainable alternatives to toxic chemicals and help industry switch to using them.

The first draft should be available in early 2020 for a review by the group members, Marie-Ange Baucher, administrator at the OECD environment directorate, told Chemical Watch. The report will then be published towards the end of 2020 or early 2021, she added.

The OECD Ad Hoc Group on the Substitution of Harmful Chemicals was established in 2012. It is co-chaired by the US EPA and Echa, and members include government agencies, industry, academics and NGOs.

Speaking at Echa's substitution and innovation network meeting in Helsinki on 29 May, Ms Baucher said the guidance would set out the principal criteria for what constitutes "safer" within an alternative assessment/substitution process. This would enable comparative hazard and exposure assessments, and risk considerations.

It would also articulate the different trade-offs encountered during the process and the types of decision-making methodologies that could be used, she said. A draft structure of the guidance also includes:

- a self-assessment checklist for practitioners; and
- a section on sustainable substitution to capture aspects such as the circular economy, life cycle, cost and availability.

The guidance may mention specific substances and their safer alternatives, but only to exemplify some of the points made, Ms Baucher said.

The ad hoc group is currently in the process of collecting a list of priority chemicals and groups of chemicals identified for alternatives assessment and substitution across different countries and regions.

Regulatory activity around chemicals globally is increasingly focusing on substitution amid reports that companies have been slow to take up safer alternatives to substances considered to be harmful to humans and the environment.

In Europe, Echa has a strategy in place to promote substitution, while EU member states and NGOs have also rolled out various initiatives to accelerate substitution.

Clelia Oziel

Europe correspondent

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- Resource issue kills Echa 'user-friendly' alternatives data plan
- Belgium advised to create SVHC substitution strategy

Substance bans just one risk management option, says US EPA's Dunn

Agency focused on risk communication under TSCA

6 June 2019 / Substances of concern, TSCA, United States

The US EPA is exploring risk management tools beyond simply banning substances of concern under TSCA, according to recent remarks from chemicals safety head Alexandra Dunn.

Speaking on a podcast from law firm Bergeson & Campbell, the Office of Chemical Safety and Pollution Prevention Assistant Administrator addressed possible risk management actions that will be pursued if the EPA determines any of the first ten substances subject to risk evaluation under the reformed TSCA presents an unreasonable risk.

And while the conversation around these substances – including asbestos – often returns to the concept of a ban, she said, TSCA gives the agency "a lot of ways to manage a risk."

In some circumstances, like with consumer applications of methylene chloride, the agency might determine that a ban is the only way to remove that unreasonable risk, she pointed out.

"But with some of these other chemistries, there might be lots of ways to mitigate that risk or manage that risk," she said. This could involve notifications, process controls, volume management or labelling.

"I think there's this sense on the street that EPA is looking at these chemistries with the intent that we're going to ban them all at the end of the day," she said. However, "I don't think that will be the result".

Risk communication

But Ms Dunn noted risk communication is a challenge for the agency. And she said it will be interesting to see how the agency's risk management decisions are received as they start rolling out.

"In our world, we do use things that are dangerous, things that have very, very devastating side effects if they are misused," she said. "But we also know how to use things safely."

TSCA, she continued, is a risk-based statute, and it will be important for the agency to talk about the fact that it does not take a hazard-based approach.

"Our job is to make sure that we think long and hard about what could happen with the use of chemicals and pesticides," said Ms Dunn. "We're working hard to look at every place where there could be a risk and address it."

But she noted that many of these risk mitigation activities will take place around hazardous substances and the agency needs to work to communicate that we live in a society that is full of risks.

"Things don't go away just because they're hazardous," she added.

Kelly Franklin

North America editor

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- EPA names first ten chemicals for new TSCA evaluations
- ACC: asbestos ban would create a 'significant shortage of chlorine'
- US EPA bans methylene chloride in consumer paint removers

Alternatives providers seek better access to EU market

Help needed from authorities to 'emancipate' REACH

6 June 2019 / Alternatives assessment & substitution, Europe, REACH, SVHCs

Providers of alternatives to SVHCs in the EU are "very afraid" of marketing new chemicals because they could be seen as "disruptive" by industry, the Alliance of Alternative Providers (AAP) said.

Speaking at a substitution conference in Brussels last month organised by the Dutch EU Permanent Representation, the European Environmental Bureau and consultancy Fipra, Willem Vriesendorp on behalf of the AAP said substitutes mean "shifts in the supply chain and additional costs".

In some cases, he added, actors in the supply chain have been working together for 20 years "and do not see the benefit" of change.

As a result, in being the first to attempt a change, alternatives providers fear they will be ignored by industry. They frequently face the "market disadvantage that comes from being the first, lone mover," he said.

The alliance, Mr Vriesendorp said, is an informal advocacy platform founded on request of some alternative providers to overcome these issues. It can help them be "better organised, speaking up with one voice, and avoid being too late or too fragmented".

The objective, Mr Vriesendorp said, is to "emancipate" REACH from the rigid authorisation process so that alternative providers play a part early in the process "before an application is ended, before people are entrenched".

Improving substitution is one of the European Commission's second REACH Review actions.

NGOs and authorities have warned that the process is inadequate, and some companies are reluctant to switch to safer alternatives. Instead they tend to ask for authorisations to continue using SVHCs.

Support

To enhance supply chain reception of substitution, alternative providers should not push their case too quickly, Mr Vriesendorp said.

"We should not go from 1 to 200 substitutes in one day. It should be progressive. We should speak about it and see how to proceed," he added.

To help level the playing field between SVHC providers and those supplying alternatives, more support from the Commission and Echa is needed.

The EU bodies should "take a greater account of alternative providers" at an earlier stage, and better understand the "difficult" situation they are in, he added. "It is difficult to cross the 'valley of death' for new products if the journey is too long."

In separate comments to Chemical Watch, Frida Hök from NGO ChemSec said that Echa and the Commission "should make very clear that industry needs to start looking for alternatives earlier" and to "be prepared" for the authorisation process.

To provide a "clear" message, the EU executive must only grant authorisations when alternatives are not available, she added.

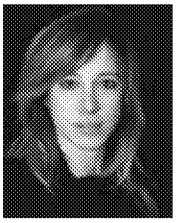
Substitution and innovation can be "more efficient" when a substance is on the candidate list, or even the NGO's Substitute It Now SIN list, not when a substance moves to Annex XIV", and companies "start to panic".

In 2017, Chemsec launched the Marketplace, an online platform for promoting safer alternatives, which has "many contacts" with AAP, Ms Hök said.

The Alliance of Alternative Providers (AAP) is an informal platform which gathers companies together to press their case for substitution.

Created one year ago, it includes companies of different sizes and positions in the supply chain, which "feel more comfortable by operating together", under a more "neutral banner". It "is a tool for organising advocacy around certain concrete cases", Mr Vriesendorp said.

For instance, in September 2018 the AAP called for shortening of the review period for chromium trioxide from twelve to seven years, and, last February, it suggested that the Commission makes 2020 the European year for substitution.



Caterina Tani

Europe reporter

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- Belgium advised to create SVHC substitution strategy
- NGO Platform: The usual suspects: time to move beyond the most obvious SVHCs
- ChemSec launches online marketplace for safer alternatives
- REACH authorisation application rejected in EU first

Further Information:

- Alliance of Alternative providers call

Trade groups call for exclusion of ADCA from REACH authorisation

Associations urge worker threshold limit instead

6 June 2019 / Aerospace, automotive & engineering, Built environment, Chemical production & transport, Electrical & electronics, Europe, REACH, Sensitisers

Trade associations covering the plastics, rubber, automotive and flooring sectors are calling on the European Commission to set an occupational exposure limit value for the substance ADCA, instead of adding it to the REACH authorisation list (Annex XIV).

In February, the Commission published a draft regulation to add 12 substances of very high concern (SVHCs) to the list, including ADCA. It has proposed to adopt this in October, according to a WTO notification filed on 15 February.

The substance was added to the candidate list of SVHCs for authorisation for its respiratory sensitising properties in 2012.

ADCA is a blowing agent used to make plastic and rubber products. Many end up in articles used by sectors such as building and construction, automotive, electronics and consumer products.

During a Commission consultation on the draft , 66 organisations and companies submitted comments, many opposing the substance's inclusion. Comments included from:

- the European Tyre and Rubber Manufacturers Association (ETRMA);

- European Plastics Converters (EuPC);
- the European Resilient Flooring Association (Erfi)
- the European Automobile Manufacturers Association (Acea); and
- the Japan Rubber Manufacturers Association (JRMA).

These trade bodies said that any potential risk associated with ADCA is "strictly limited to industrial sites" because the substance is fully embedded within the polymer or rubber matrix.

They said therefore end users are "typically not exposed", which makes setting an OEL the "optimal risk management option".

Currently, in the UK there is an OEL set at 3mg/m^3 for short-term exposure (15 minutes) and 1mg/m^3 for long-term exposure (8-hour average). In Finland, the OEL is 0.5mg/m^3 for long-term exposure.

However, Tatiana Santos of NGO the European Environmental Bureau said because the substance is classified as a respiratory sensitiser category 1, it is a "non-threshold chemical for which no safe level of exposure can be established".

An OEL is meaningless, added Ms Santos. "It would not help people, particularly workers exposed to ADCA, avoid respiratory allergies including asthma".

The JRMA said that an SVHC identification – and inclusion in Annex XIV – would have adverse effects on the "global supply chain and smooth international trade".

And Acea said adding it to the authorisation list would have a negative economic impact on automotive manufacturers and plastic and rubber producers. The result could see investment in materials, equipment and vehicles being focused outside of the EU, it said.

Alternatives

The sector groups say they have been trying to identify substitutes. The associate members of JRMA conducted a study on the alternatives, "but no substances have been found to date".

Erfi said: "Currently there is no known alternative which can achieve the same quality and properties of the end product."

And the ETRMA said forcing the use of substitutes through REACH authorisation is "impossible to achieve for rubber producers" when research by the sector has failed to find alternatives.

"Manufacturers of rubber products using ADCA will irremediably be forced to apply for an authorisation for the use, an expensive, tedious and uncertain process, which only grants access for a limited period, if granted," it said.

'Multiple delays'

Ms Santos said the Commission has "not properly justified multiple delays" to include the substance on the authorisation list, following its inclusion in the candidate list in 2012.

"The Commission's failure to act meant that European citizens and the environment continued being unnecessarily exposed to this dangerous substance," she said.

This delay, added Ms Santos, prevents REACH from achieving its core goal of ensuring that the risks from SVHCs are properly controlled. And that these substances are progressively replaced by suitable alternatives or technologies, where these are economically and technically viable, as set out in REACH Article 55.

"It is time the Commission is held accountable to the European public for protecting citizens and the environment from hazardous chemicals and should act without delay by including ADCA in Annex XIV," she said.

"Putting a substance on the authorisation list should be a scientific decision, not a political consideration," added Ms Santos.

In response, a Commission source said REACH does not set any deadline for the inclusion of substances recommended by Echa in Annex XIV.

Echa recommendations are not binding on the Commission, according to the source. The decision not to include ADCA at an earlier stage was based on several considerations, including socio-economic and practical ones, they said.

The Commission is currently analysing the comments received. A discussion on the proposal and results of the consultation are planned for the REACH Committee on 9-10 July.

Leigh Stringer

Global Business Editor

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- EU to add 12 substances to REACH authorisation list

Further Information:

- Consultation comments

Echa MSC agrees to exposure requests under Corap

Tests for nanomaterials in car brake pads

6 June 2019 / Aerospace, automotive & engineering, Europe, Exposure monitoring & measurement, Nanomaterials, Risk assessment

Echa's Member State Committee (MSC) has decided that member states can request exposure information during substance evaluation under the Community Rolling Action Plan (Corap).

But the question remains over whether the substance evaluation process is the "most efficient or effective" way to request exposure data, because REACH registration and authorisation include use and exposure data, said MSC chair Watze de Wolf.

At its meeting on 14-16 May, the MSC discussed substance evaluation cases for zinc oxide and potassium titanium oxide. As the evaluating member state, Germany has requested specific information on nano zinc oxide uses and the MSC also agreed to long-term environmental toxicity testing.

"The testing is very much to determine whether or not the zinc ion is responsible for toxicity or if the nanoform itself could give an increased toxicity," said Dr de Wolf.

Meanwhile, France is evaluating potassium titanium dioxide, used in automotive care products and car brake pads. The substance can contain fibres that meet World Health Organization (WHO) criteria for biopersistence.

Such fibres are longer than five microns, with a diameter under three microns and a length-to-diameter ratio exceeding 3:1. "WHO fibres have carcinogenic potential and the question is whether they are formed from the use of the registered substances, or possible applications that they are used in, or whether the registered substances already contain a certain amount of WHO fibres," said Dr de Wolf.

France has requested new tests to simulate brake pad use and look for the fibres. The MSC discussed whether or not registrants should supply information, given that brake pads may only be made by downstream users. Registrants "will need to perform the simulation tests if this does not go beyond their control," said Dr de Wolf. In other cases, "it's up to downstream users to ensure that no WHO fibres are generated," he added.

If the tests show that these are generated, or are at levels above 0.1% in the product, then a 90-day chronic inhalation toxicity study will also be required.

New Eloc combinations

The MSC also had a general discussion on "new combinations of properties" that may give rise to an equivalent level of concern (Eloc) under REACH Article 57f.

Members discussed a 'mobility' category for substances that can travel long distances in the environment. The committee will soon return to the fluorinated substance GenX, which is claimed to be mobile in the environment.

Last December, Germany withdrew a proposal to identify perfluorohexanoic acid (PFHxA) as a substance of very high concern (SVHC) for persistence and mobility. This was after the UK and Finland raised concerns about interpreting REACH's equivalent level of concern (Eloc) principle for environmental pollutants.

The country is instead preparing a restriction proposal, amid concerns over persistence, bioaccumulation and toxicity (PBT).

Dr Emma Davies

Reporter

Related Articles

- Dutch SVHC action against GenX is 'first of kind'
- UK, Finland dissent led to withdrawal of PFHxA SVHC proposal

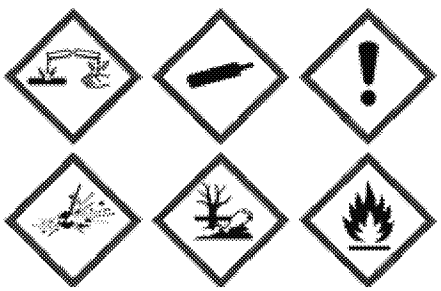
Further Information:

- MSC agenda for 64th meeting

Australia to consult on adopting GHS 7

Update would help align with 'key trading partners'

6 June 2019 / Australia, GHS



Safe Work Australia (SWA) has announced that, in the coming months, they will conduct a public consultation on adopting an updated edition of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) for workplace hazardous chemicals.

Most Australian jurisdictions adopted the third revision of GHS on 1 January 2017 and SWA is now proposing to move to the 7th edition in order to align with "key trading partners," it says. Further information is expected in July.

SWA is the national body responsible for the development and evaluation of 'model' work health and safety laws, but it is not a regulator. Australian states and territories can choose whether or not to adopt the model laws as legislation.

In October SWA also updated its national guide to classifying hazardous chemicals for the first time in six years. SWA told Chemical Watch this was to reflect the current regulatory arrangements in Australia.

For further GHS developments Nhat Nguyen, Chemical Watch's chief analyst, and Cristina Garcia, regulatory and compliance analyst, discuss global developments as countries adopt the sixth or seventh edition of GHS.

Related Articles

- Understanding GHS in Australia
- Safe Work Australia updates hazard classification guide
- 2019 Global Outlook: Key GHS developments

Further Information:

- SWA announcement

Retailers prioritise product categories for developing safer alternatives

Transparency plan includes short- and long-term disclosure recommendations

6 June 2019 / Alternatives assessment & substitution, Retail, United States, Voluntary action

A group of US retailers has called on manufacturers to develop safer alternatives for certain priority product categories sold at stores and depots.

These include:

- flame retardants, used in indoor and outdoor furniture, textiles, electronics and carpeting;
- plasticisers, used in cleaning and personal care products, office supplies, home improvement, electronics and textiles;
- preservatives and antimicrobials, used in cleaning and personal care products, baby products, office supplies and electronics;
- solvents, used in removers for paint, ink, and graffiti;
- surfactants, used in cleaning and personal care products; and
- water and stain repellents, used in food packaging, indoor and outdoor furniture, home improvement, apparel and footwear and carpeting.

The Retail Leadership Council (RLC), a group within US organisation the Green Chemistry and Commerce Council (GC3), spearheaded the move to "collectively identify a set of chemical and application priorities for innovation in safer alternatives." The RLC is a coalition of ten major retailers, including Amazon, Best Buy, CVS Health, The Home Depot, Staples, Target and Walmart.

The companies have also laid out their transparency goals and best practices for the coming years.

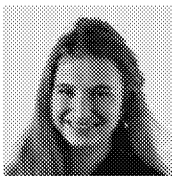
In the short-term (2019-2020), this focuses on transparency along the supply chain to the retailer. The road map emphasises "disclosing all intentionally added ingredients including components of generics such as fragrance and flavour" to retailers, as well as using a "threshold of 100 parts per million (ppm) in finished product (except when regulations are more stringent)".

In the longer term (2021-2022) the RLC recommends expanding these transparency practices to the relationship between the retailer and the public. And past 2022, it says best practices should include no threshold for disclosing "all intentionally added ingredient components of formulated products."

Several NGOs applauded the move. Mike Schade, director of the Safer Chemicals Healthy Families' Mind the Store Campaign, said: "Brands and chemical manufacturers across global supply chains should pay close attention to this new list and then develop and transition to safer alternatives."

And Laurie Valeriano, executive director of Toxic-Free Future, pointed out that the list comes as more states move to phase out certain priority chemicals, such as halogenated flame retardants.

"Washington's new law will drive the market to safer alternatives, so getting ahead of the curve makes a lot of sense," Ms Valeriano said.



Lisa Martine Jenkins

Americas reporter

Related Articles

- The GC3: stakeholder collaboration on safer products
- Washington state: 'Nation's strongest' chemicals in products policy becomes law

Further Information:

- RLC Statement

US EPA round-up

6 June 2019 / PFCs, United States

Science Advisory Board convenes

The US EPA requested input from its Science Advisory Board (SAB) on its controversial 'science transparency' proposal when the body convened in Washington, DC on 5 June.

More specifically, the agency has sought feedback on how to handle confidential business information (CBI) and personally identifiable information (PII) under the proposed rule, which seeks to ensure that science underlying agency regulatory decisions is available for public review.

It requested SAB comments on these topics before the end of this summer, with plans to convene a teleconference with the advisory board in mid-summer.

During the two-day SAB meeting, EPA representatives also raised the subject of updating the agency's 2005 cancer risk assessment guidelines and developing noncancer assessment guidance.

The EPA also asked for the advisory board's input on its per- and polyfluoroalkyl substances (PFAS) action plan.

Agency watchdog to evaluate enforcement activity

The EPA Office of Inspector General has announced that it plans to begin fieldwork on an analysis of the agency's enforcement results from fiscal years 2006 to 2018.

This constitutes the second notification of the OIG project, though the objectives have been slightly modified since the initial November 2018 memorandum.

House oversight committee to conduct hearing on EPA's direction

The House of Representatives' Oversight and Investigations Subcommittee will hold a hearing on the "direction of the EPA". This will convene a bipartisan group of former EPA administrators to examine the mission and future of the agency.

It will take place on 11 June in Washington, DC.

Related Articles

- US EPA looks to move on controversial science transparency rule
- US EPA announces PFAS action plan

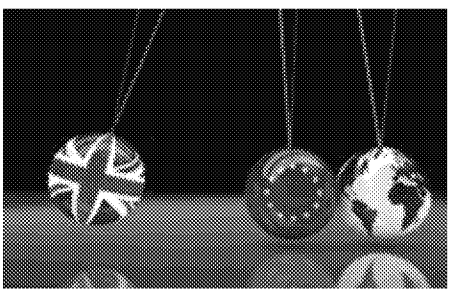
Further Information:

- SAB agenda
- OIG project notification
- House hearing

UK may act faster on post-Brexit substance restrictions – minister

New chemicals strategy will consider EDCs, but 'balance needs to be right'

6 June 2019 / Alternatives assessment & substitution, Brexit, REACH, SVHCs, UK



The UK may be able to restrict and phase out some chemicals faster than the EU after Brexit, but it has to "get the balance right" when regulating endocrine disruptors, according to a junior minister.

Thérèse Coffey MP from the Department for the Environment, Food and Rural Affairs (Defra) told a parliamentary hearing on 5 June that the UK's post-Brexit approach would be to address priority chemicals in groups and the combination effects of different substances.

On some things, such as decaBDE, she said "I would like to think that we may be able to act more quickly".

It took more than five years to restrict the flame retardant in the EU, Dr Coffey said, even though the UK had been pressing for action since 2012.

She was answering MPs' questions at the fourth and final oral evidence session of the Environmental Audit Committee (EAC) inquiry into the impact of toxic chemicals in everyday life.

Defra is due to start work on a new chemicals strategy, to be finalised in 2020 or 2021, and this will "certainly include" a consideration of endocrine disrupting chemicals, Dr Coffey said.

However, when asked what the UK position would be given that France, Denmark and Sweden have taken a tough line and called for a ban on EDCs, she said "we have to get the balance right. Even things like lavender oil have chemicals in them which are EDCs and lot of this is about the dose of what is there, how it interacts and how we manage the risks," she told the committee.

It is "frustrating", she added, that some EU countries take a much more hazard-based approach and are "not always led by scientific evidence".

The UK is currently due to leave the EU on 31 October. If a withdrawal deal is not approved in parliament by then, and the departure date is not extended further, it will exit on WTO terms and set in motion a UK version of REACH.

UK candidate list

In tackling SVHCs, the UK may in some cases bring them to a version of the candidate list earlier than the EU, Dave Bench, director of EU exit – chemicals at the Health and Safety Executive (HSE), told the inquiry.

The future UK candidate list would look very similar in some respects to the EU list, he added, but the government would need to decide if it "wanted to do work ourselves in advance of the EU doing it".

The UK may also want to conduct an "additional UK-only assessment" or an additional assessment to determine "whether we would want to make exactly the same decision or a decision that is similar but a bit different and bespoke for UK conditions".

The EU approach on sunset dates for phasing out SVHCs is "sensible", Dr Coffey added, but there may be opportunities for the UK to accelerate them "where we have some strong signs and really want to push on with it".

Grouping chemicals

Grouping of substances for evaluation purposes will play a key part in the new chemicals strategy, Dr Coffey confirmed.

Mr Bench said it is also important to closely consider chemicals that are structurally different but applied to the same or similar uses to prevent regrettable substitution.

In a no-deal Brexit scenario, he said, the UK would agree on a work programme of substance evaluations. It may, he added, push substances of concern from a UK perspective "up the list" and evaluate them more quickly, while waiting for EU decisions on others.

Clelia Oziel

Europe correspondent

Related Articles

- NGOs battle EU Commission over POPs flame retardants definition
- Post-Brexit skills shortage could hamper UK chemicals agency
- UK agency head grilled on hazardous chemicals controls in FCMs
- England to launch new chemicals strategy
- EU ministers push Commission to speed up EDC strategy
- UK publishes amended draft REACH SI
- UK committee probes Amazon, Ikea, Kingfisher on chemicals management

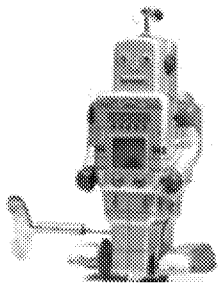
Further Information:

- Inquiry
- Hearing

AI poses challenge to method validation, says senior OECD figure

Algorithms not transparent because they change 'from one day to the other'

6 June 2019 / Data, Global, Test methods



The incorporation of artificial intelligence, or machine learning, into *in silico* methods of hazard prediction presents a new validation challenge, according to a senior OECD figure.

At the Helsinki Chemicals Forum on 31 May, Bob Diderich, head of the OECD's environmental health and safety division, which runs the test guidelines programme, said that he did not yet have an answer.

Developers of *in silico* methods are increasingly working with machine learning because of the possibilities it raises. In theory, methods incorporating this technology improve as they are used because the underlying algorithm changes constantly in response to new data.

Mr Diderich said that the OECD has been working on validation of *in silico* methods for several years with the aim of increasing use and acceptance for regulatory purposes.

"What's the kind of validation that we need and who's going to do it? Can we have something for Qsars [quantitative structure-activity relationships] that is similar to what we have today for laboratory test methods?" he said. "The conclusion of that discussion was these methods evolve way too fast. By the time we've put a stamp on it, there's another model that is way better."

The conclusion at that time was to provide the principles of validation – such as *OECD principles for the validation, for regulatory purposes, of Qsar models*, published in 2004 – and shift the validation challenge onto the developers.

"If you [the developer] want mutual acceptance of data, you need to demonstrate how the validation criteria are fulfilled," Mr Diderich said.

"But now artificial intelligence comes along, meaning there is no longer a transparent algorithm, because it changes from one day to the other. How do we deal with that?"

Defined approaches

Mr Diderich said that, so far, validation of *in silico* methods "has not taken off as much as we had hoped."

Meanwhile, the challenge of validating them has become more pressing as the OECD's work on defined approaches (DAs) has progressed. Defined approaches are a solution to the limited scope of most non-animal test methods, which generally have to be combined in some way to answer a specific scientific question, such as: does this substance cause skin sensitisation? In contrast, regulators accept that animal-based methods deliver equivalent answers when used in isolation.

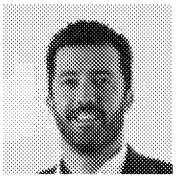
The OECD has developed a draft test guideline for a defined approach to non-animal prediction of skin sensitisation that, if approved, would become subject to the OECD's mutual acceptance of data system.

According to the Chemical Safety and Biosafety Progress Report published by the OECD in April, two expert groups, the Iata case studies team and Qsar toolbox management group, met last year to discuss this work, with particular reference to:

- the applicability domain of a DA;
- validation and transparency of Qsar methods;
- instructional information for Qsars in the context of DAs; and
- good laboratory practice (GLP) for Qsars in the context of DAs.

The group recommended "flexible levels of transparency for different users, but at a minimum, the algorithm, training set and applicability domain should be available to reviewers and regulators upon request". Additionally, there was agreement that Good Laboratory Practice (GLP) principles were not applicable to *in silico* data and that instead the data should follow a "documentation quality standard".

The steering group for the test guidelines programmes, the WNT, discussed the work in April at their annual meeting but took no decision on this occasion.



Andrew Turley

Science editor, Chemical Watch

Related Articles

- OECD TG will remove expert judgement from skin sensitisation prediction

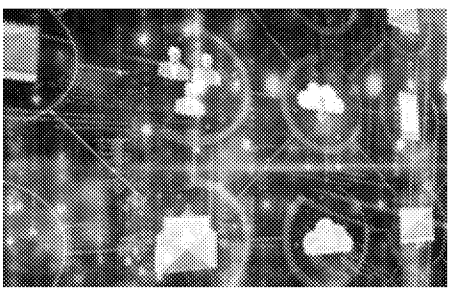
Further Information:

- OECD principles for the validation, for regulatory purposes, of Qsar models (2004)
- Chemical Safety and Biosafety Progress Report (April 2019)

Kemi expert: non-targeting screening requires new identification system

Cas and EC numbers do not provide structural information

6 June 2019 / Data, Risk assessment, Sweden



A better chemical identification system will have to be considered to detect industrial chemicals in non-targeted screening, according to a representative from the Swedish Chemicals Agency (Kemi).

"On balance, Cas [the Chemical Abstracts Service] is serving the chemical market and not so much the regulators," said Stellan Fischer, who spoke about this issue at the Society of Environmental Toxicology and Chemistry (Setac) conference in Helsinki last month. "The Cas number system is quite often for the trading of chemicals ... but authorities would like the chemical structure to be connected."

Cas registry numbers are used by many regulators and authorities for chemical identification. A representative from Cas – a division of the American Chemical Society – said that "regulatory authorities around the world choose to use Cas registry numbers as a primary descriptor for chemicals because of their specificity".

The EC number system, which is used in REACH, has the same problem of no chemical structure, added Dr Fischer. "They can have seven structures connected to the one EC number, so one number is not necessarily one molecule."

Historically, regulators "thought it was enough to know the main constitutes," said Dr Fischer. They are now interested in knowing what specific molecules are present. "We have found that most of the chemicals on the market are not clean and contain quite a lot of other molecules."

This is problematic for agencies and other authorities when they conduct non-targeted environmental screening, as many molecules do not have detailed information in regulatory databases. In many cases, they have only Cas and EC numbers.

Dr Fischer said more detailed systems are in operation, such as that developed by the International Union of Pure and Applied Chemistry (Iupac), which is used by scientists to identify chemicals at a molecule-specific level. The Iupac International Chemical Identifier or InChI system includes more information on each chemical, including its structure, coded using a string of 27 characters called an InChIKey.

Despite the potential benefits, "agencies normally don't work with InChIKeys because [the system is] so new and we are forced to follow our regulations," Dr Fischer said. Furthermore, regulatory databases are not enabled for these newer types of chemical IDs and the administrators of those databases would have problems trying to implement them.

Instead of replacing Cas numbers with InChIKeys, Dr Fischer proposed using the latter "as a complement to better understand what's behind a Cas number." Translation tools would be needed to go from the Cas number to the InChIKey, other chemical IDs and structural information.

"One good attempt is the Chemical Dashboard that the US EPA is building," said Dr Fischer. This allows users to search with a Cas number or InChIKey to find out more information about the relevant chemical.

Cas responded saying that "regulatory bodies each decide how to describe and regulate complex commercial products versus individual chemical substances." They added: "CAS partners closely with many global regulatory authorities, as well as commercial submitters, to support their application of Cas registry numbers within these systems."

Maria Delaney

Reporter

Further Information:

- InChI system
- Chemical Dashboard

Echa round-up

6 June 2019 / Europe

Communications Strategy 2019-23

Echa has published its communications strategy 2019-23. In it the agency identifies five priority focus areas aimed at responding to the challenges of the "changing communications landscape".

These priorities are to:

- increase the agency's visibility as a centre of knowledge on chemicals safety and relevant EU legislation;
- aim for a "more approachable tone of voice";
- increase engagement with mainstream media and key stakeholders;
- contribute to getting the most out of the agency's data and competences by increasing its visibility and usage; and
- encourage employee advocacy and involvement.

The agency says it intends to tailor communications in language that is relevant and easy to understand, and communicate through the right channels and networks.

Chemicals in a circular economy

The agency has created a new web page on *Chemicals in the circular economy* that looks at action being taken across the EU to encourage clean material cycles and reduce the use of hazardous chemicals. The page includes a short animation, explaining why chemicals are key and need to be dealt with properly.

Feedback on news products

Echa's reader survey on improving the content of its news products is set to close on 12 June. As well as using its website, newsletter and weekly news to disseminate information, the agency uses various social media outlets too including Facebook, Twitter and Youtube.

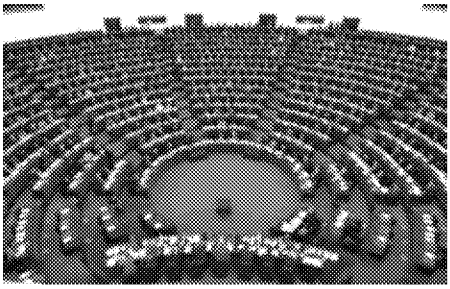
Further Information:

- Communication strategy
- Chemicals in a circular economy
- News products

Greens' EU parliament success could elevate chemicals agenda

UK voting advances possibility of no-deal Brexit

6 June 2019 / Brexit, Europe, Substances of concern, UK



The growth of the Greens/European Free Alliance political group in last month's EU parliamentary elections could turn up the pressure on the next European Commission to take more regulatory action on chemicals.

In the elections, the Christian Democrats (EPP) won a slight majority over the socialists and democrats (S&D), while the Liberals and Democrats for Europe (ALDE&R) came in third.

However the result also saw a particularly strong showing by the Greens, who will now see their presence in European parliament grow by almost 50%, with their MEPs holding close to 10% of all seats.

This is expected to give them greater influence in the Parliament where, according to the Greens/EFA group's advisor Axel Singhofen, they have been the "driving force" on the issue of hazardous chemicals regulation.

Mr Singhofen highlighted to Chemical Watch the role the group had already played including:

- objecting to five REACH authorisations and pushed for Echa's database of SVHCs; and
- helping organise the Parliament veto against modifications of the pesticides regulation in the context of establishing scientific criteria for endocrine disruptors.

And he added "there is more to come".

One area where the Greens will be able to exert greater influence is on the European Parliament's environment committee (Envi), where they will now have an increased number of seats.

And key German Green party member Sven Giegold is expected to move to Envi "to maintain and up the pressure on the Commission to ensure compliance with REACH and achieve effective follow-up to the recent Parliament resolutions", Mr Singhofen said.

"He may well be joined by further members of the Greens with a thorough chemical background and strong interest in improving chemical regulation."

Others too were quick to note the Greens' success. Tatiana Santos, policy manager at NGO the European Environmental Bureau, said voters "have confirmed what poll after poll showed – we do care about health and environmental protection and this is a clear call for the EU policy makers to prioritise protection".

Voters "have confirmed what poll after poll showed – we do care about health and environmental protection and this is a clear call for the EU policy makers to prioritise protection"

CHEM Trust campaigner Kate Young said the "real test" for the next Commission will be to "urgently address the many problems" with chemicals policy including food contact materials.

And Cefic said it looks forward to working with the new European Parliament. "Given the outcome of the elections, it will be even more important to work with a broad group of MEPs."

The new Parliament is due to hold its inaugural meeting on 2 July. It will vote on a nominee for European Commission president, who will take office on 1 November.

Brexit implications

In the UK more citizens backed green MEPs in the election than previously, but the Brexit party and UKIP had 35% of the vote, increasing the possibility of a no-deal Brexit. Following President Trump's state visit to the UK this week the door to a trade deal with the US appears to have been opened a little.

But Mr Singhofen said it would be "madness" if Brexit means the UK abandons REACH-level protection. "US rules on chemicals are of the last millennium and have proven to be utterly unfit."

And Ms Santos said weaker rules would risk the UK becoming "a place where obsolete chemicals would continue to be produced" while the EU moves forward with safer alternatives. It would also, she added, "undermine" protection of EU27 citizens as SVHCs could still enter the EU market through consumer articles from the UK.

Meanwhile, Chemical Industries Association chief executive Steve Elliott said he will "work with whoever is in charge and pursue" the trade body's agenda of delivering a chemical industry that "continues looking for innovative solutions".

Duplicating or diverging from efforts made over the previous decades "would only set back our sector's capability to deliver those new solutions and technologies to help meet today's and tomorrow's societal challenges", he added.

Duplicating or diverging from efforts made over the previous decades "would only set back our sector's capability to deliver those new solutions and technologies to help meet today's and tomorrow's societal challenges"

The UK chemical sector, he said, welcomes any move to strengthen and facilitate export and investment ties around the world. That includes the US as the industry's largest individual trading partner, but it also includes the EU27 as "collectively the most important" location for UK chemical businesses.

"With that in mind, we continue to focus on a new future trade and investment relationship with the EU as our first priority – more certainty around which will help in time facilitate a future UK/US free trade agreement."

UK prime minister Theresa May's leadership of the Conservative party will come to an end on 7 June, but she will remain as the prime minister until a replacement has been chosen. This is expected by the end of July.

Luke Buxton

Europe editor

Related Articles

- Development of Echa SVHC database resumes after resources agreed
- European Parliament rejects EDC criteria
- EU Parliament urges next Commission to 'swiftly' tackle EDCs

Echa considers adding POPs information to pre-regulatory notification list

Early communication would help industry preparations, says Cefic

6 June 2019 / Chemical production & transport, Europe, POPs

Echa says it may add information on substances being proposed as persistent organic pollutants (POPs) to its public activities coordination tool (PACT). A decision is expected by the end of the year.

The PACT lists substances that an EU Member State or Echa is examining, and includes information on preparations to carry out a hazard assessment and proposals for regulatory measures. Its aim is to increase the transparency and predictability of authorities' work leading up to the more formal REACH and CLP processes.

While REACH addresses substances identified as persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB), officially recognised POPs are regulated under the EU POPs Regulation. This has meant that POPs proposals have not featured on the PACT list.

The decision to consider including proposed POPs stems from the recent recast of the EU POPs Regulation. This aligns the regulatory procedures of the Regulation with the requirements of the Lisbon Treaty and gives Echa new tasks. It also introduces recent decisions taken within the framework of the Stockholm Convention and the Aarhus POPs Protocol.

Echa's new tasks are related to the preparation of the EU's proposals on new POPs. The process from proposing a substance to its inclusion in the POPs regulation takes several years, the agency told Chemical Watch.

"Echa is expected to communicate about such preparations ... PACT is one option for that purpose," it added.

Cefic told Chemical Watch that an early notification of ongoing or preparatory work on a substance will "facilitate cooperation" between authorities and industry and help companies prepare any additional information/data in advance, if needed.

The PACT is useful, it says, because it indicates all regulatory activities undertaken for a substance, for example, the status of a public consultation.

"The POPs Recast makes it mandatory for Echa to organise a public consultation on a POP dossier so this kind of information would be available through PACT," Cefic said.

While this would be useful, Cefic urges Echa to go "one step further" and conduct a risk management options analysis (RMOA) before the PACT is updated.

This would "confirm whether a POP nomination is the best instrument to manage risks associated with the use of a certain substance" and would allow all member states to take an informed decision on the most appropriate risk management measure.

The recast was triggered when the toxicology committee for the Regulation ceased to exist in 2015 because of changes to its legal basis, creating the need to adapt the provisions concerning comitology.

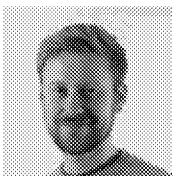
REACH vs EU POPs Regulation

The POPs Regulation is tasked with implementing relevant international treaties and takes precedence over REACH, so as not to weaken global measures to address POPs.

For example, REACH authorisation cannot be granted for a substance that has been officially classified as a POP under the EU's Regulation.

REACH states that "if a use of a substance is subsequently prohibited or otherwise restricted in [the EU POP Regulation], the Commission shall withdraw the authorisation for that use".

Additionally, once a substance is added to the EU POPs Regulation, restrictions under REACH Annex XVII and granted exemptions are superseded by the related obligations of the POPs Regulation.



Leigh Stringer

Global Business Editor

Related Articles

- Envi committee approves EU POPs recast

Further Information:

- PACT
- POPs recast

Expert Focus: Poison centre Annex VIII member state implementation plans

7 June 2019 / Accidents, emergency response & poison centres, CLP Regulation, Europe

Caroline Raine, technical associate director a the National Chemical Emergency Centre, provides an overview of EU member state approaches to CLP Annex VIII. Ms Raine will be speaking at the Chemical Watch Expo 2019: Global Chemical Regulations conference in Brussels on 12-13 June.

On 24 April Echa released its submission system for poison centre notifications to member states under the Annex VIII to CLP harmonised format.

Annex VIII was published in March 2017 and requires all hazardous mixtures for health or physical effects to be notified to member state poison centres.

The Annex VIII deadlines are phased; with the first being for consumer mixtures in January 2020, followed by January 2021 for professional use mixtures, and January 2024 for industrial use.

Any mixtures that have been previously notified to member states can benefit from the transitional period, which ends 1 January 2025.

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Annex VIII specifies the harmonised format for notifications and introduces the requirement for a Unique Formula Identifier (UFI) to be created for every mixture. This is then included on the label and the SDS. Also introduced is the European Product Categorisation System, which is used to describe "the intended use of a mixture" and will be used by member states to facilitate reporting and monitoring of poisoning incidents at the EU level. Both the Product Categorisation System and the UFI are required as part of the notification.This article explores the status of the implementation of Annex VIII across member states and discusses the benefits of notifying now to maximise the benefit of the transitional period.

Member state implementation

Prior to Annex VIII, each member state had implemented their own systems for receiving notifications of hazardous mixtures. Some are free, some charge fees, some require the use of an electronic security certificate, many are happy to receive information via email, whilst others have their own web portals.

 So it is no surprise that although Annex VIII harmonises the information that must be provided, each member state still intends to do things slightly differently.

When the harmonised submission system was released, a document was also made available on the Echa Poison Centre's website, *Overview of member states decisions in relation to implementation of Annex VIII to the CLP Regulation*. This document is available on Echa's poison centre website. Let us have a look at the member state implementation intentions in a little more detail.

Submission system

Member states have two options – they can either just use the Echa submission system, or they can continue to accept notifications via either their own system or the Echa submission system. Three countries have chosen the latter option and plan to use their own system or Echa's: Austria, Germany and Portugal.

Most countries have chosen to go with only the Echa submission system, but several member states have yet to make public their intentions including France. Given that France have their own well-established system, it would not be surprising if they planned to continue to use it.

Countries intending to use their own notification system and the Echa submission system	Austria, Germany, Portugal
Echa submission system only	Croatia, Cyprus, Denmark, Estonia, Finland, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Norway, Poland, Slovakia, Slovenia, Spain, Sweden
No information provided	Belgium, Bulgaria, Czech Republic, France, Iceland, Liechtenstein, Luxembourg, Romania, UK

Notification language

The Echa submission system allows notifications to be prepared in the country's own language and it then translates the notification into other member states languages. Unfortunately, this does not extend to the toxicological information which must be provided (section 11 of the SDS). This remains as free text that must be translated by the notifier. It is worth noting that translations are only built into the online submission system; if a company plans to prepare notification files using the stand-alone IUCLID software, it does not have the built-in translations.

Official member state language only	Austria, Bulgaria, Czech Republic, Denmark, France, Greece, Hungary, Iceland, Liechtenstein, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia
Official member state language or English	Belgium, Croatia, Cyprus, Estonia, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Spain, Sweden, UK
Other	Finland (Finnish and Swedish)

Fees for notification

Under the current system, several member states charge fees for notifications: Belgium, Croatia, Sweden, Finland, Ireland, Hungary, Italy and Norway. Under the Annex VIII harmonised notifications only Croatia and Spain say they are considering fees.

All the other member states have either indicated that there will be no notification fees, or that they will be levied by the member state's appointed body. The remaining nine member states have not yet indicated if they will charge fees or not.

Given that the implementation of Annex VIII is likely to impact the poison centres significantly, I would not be surprised if more member states start to introduce fees.

Placing on the market mixtures notified via Echa submission system

Germany, Italy and Spain have indicated that before a duty holder can place a mixture on the market, the member state appointed body must be downloaded the notification from the Echa system. The duty holder would be made aware when this has happened via a submission report in the Echa system.

'For Germany, Italy and Spain in particular, it is important to ensure companies notify with sufficient time before the product is put on the market'

Therefore, for Germany, Italy and Spain in particular, it is important to ensure companies notify with sufficient time before the product is put on the market.

Countries that must have downloaded the notification before duty holder can place on the market.

Countries that must have downloaded the notification before duty holder can place on the market	Germany, Italy, Spain
Duty holder can start placing mixture on the market immediately after confirmation of successful submission	Austria, Croatia, Cyprus, Denmark, Estonia, Finland, Greece, Hungary, Ireland, Latvia, Lithuania, Malta, Netherlands, Norway. Poland, Portugal, Slovakia, Slovenia, Sweden
No information provided	Belgium, Bulgaria, Czech Republic, France, Iceland, Lichtenstein, Luxembourg, Romania, UK

Timeline for acceptance of notifications via Echa submission system

This still remains rather vague; member states have either indicated that they will accept notifications between 24 April 2019 and 31 December 2019, or they have indicated that they will accept them from 1 January 2020. To date, no member states can accept notifications in the new format – so, who knows what is meant by April to December?

In addition, a number of countries require a change in their own national legislation before a date can be determined and several member states have not provided any information.

Countries that require a legislation change	Austria, Italy, Lithuania, Slovakia, Spain
Will accept notifications between 24 April 2019 and 31 December 2019	Estonia, Germany, Greece, Malta, Norway
Will accept notifications from 1 January 2020	Croatia, Cyprus, Denmark, Finland, Hungary, Ireland, Latvia, Netherlands, Poland, Portugal, Slovenia, Sweden
No information provided	Belgium, Bulgaria, Czech Republic, France, Iceland, Lichtenstein, Luxembourg, Romania, UK

Readiness of member states to accept notifications via Echa's submission system

In short, no member states are ready to accept the notifications in the new harmonised format and Jan 2020 is not that far away!

Notify now

The requirement to notify hazardous mixtures within the European member states is a mandatory requirement already in place. Waiting until the format is harmonised leaves companies non-compliant and open to penalties.

 There are a number of reasons to notify now under the current arrangements:

- it is mandatory now and enforcement is increasing across member states;
- many member states currently allow a reduced notification and therefore full composition does not need to be disclosed. This effectively buys up to seven years where full composition does not need to be disclosed – until 2025 – assuming no change is made to the declared information that would require an update within that time;
- UFI numbers on labels delayed until 2025 allow companies time to update labels in a timely manner (buying companies time to create UFIS, design and print labels);
- many member states are increasing their cost for notification and therefore delaying notifications could ultimately have significant cost implications. There are still some member states which do not charge, but as time goes on we are seeing more impose fees. The majority of poison centres do not have the infrastructure to accept the volume of notifications that are expected, in the agreed upon format. Whereas, currently two-thirds of poison centres are free to notify;
- if companies use other suppliers' mixtures in their formulation, then from 2020 they will need to include their UFI in the submission. Therefore, if a supplier makes any change to their product, that would require an update to their notification (such as change in composition, classification, etc.) and then they would need to generate a new UFI, which could trigger an update to the company's own notifications; and
- notification for some companies is going to be a hefty piece of work and any notifications that are completed before the Annex VIII deadlines are valid until 2025, assuming no change in classification after notification. Companies can buy themselves seven years to monitor these regulations and how these changes are going to affect their company.

Our advice to our clients is to notify now and benefit from the extended deadline of 2025.

Why wouldn't you notify now?

The views expressed in this article are those of the expert author and are not necessarily shared by Chemical Watch.

Related Articles

- Echa unveils poison centres submission portal
- Industry pushes Commission to extend CLP poison centre deadline

- Commission launches EU poison centre workability study
- EU CLP poison centres notification deadline 'impossible' to meet

Further Information:

- Echa's submission portal for poison centres
- CLP Annex VIII - Guidance on harmonised information relating to emergency health response
- Overview of member states' decisions in relation to implementation of Annex VIII to the CLP Regulation
- NCEC website

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